In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-290V

Filed: June 23, 2015

(Not to be published)

* *		
JULIO PAZ *and* OLGA PAZ, *on behalf of* J.P., *a minor child*,	*	
Petitioners,	*	Ruling on Record; Hepatitis A; Tdap; Meningococcal; Influenza; Hemophagocytic Lymphohistiocytosis; Encephalopathy.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Diana Stadelnikas Sedar, Maglio Christopher and Toale, PA, Sarasota, FL for petitioner.
Christine M. Becer, United States Department of Justice, Washington, DC for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

Gowen, Special Master:

On April 11, 2014, Julio Paz and Olga Paz filed a petition on behalf of their minor child, J.P., pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2006) ("Vaccine Act"). Petitioners allege that J.P. suffered a pulmonary hemorrhage, acute liver failure, acute renal failure, encephalopathy, disseminated intravascular coagulation, hemophagocytic lymphohistiocytosis ("HLH"), and resulting death, as a result of receiving hepatitis A, tdap, meningococcal, and influenza vaccinations on October 4, 2012. See Petition; see also Petitioners' Motion for Decision on the Record ("Motion") at ¶ 4, 6.

After filing five exhibits of medical records and a Statement of Completion indicating that

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 and note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

the record is complete, petitioners filed a motion for a ruling on the record on November 24, 2014. Petitioners aver that "[a]fter further analysis of the medical records, science, and expert consultation, [they] will not be filing a medical expert opinion. Motion at ¶ 7. As noted in her Rule 4(c) Report, respondent recommends against compensation in this case.

After a review of the entire record, the undersigned finds that petitioners have not satisfied the requirements of a Table encephalopathy claim, and that they have not satisfied their burden of proof as required in an off-Table claim. Accordingly, petitioners are not entitled to compensation. See §300aa-13(a)(1).

I. Procedural Background

On April 14, 2014, petitioners filed a death certificate and medical records from Massachusetts General Hospital related to their minor child J.P.'s course of illness. See Pet. Exs. 1-2. On May 20, 2014, petitioner, Olga Paz, filed an affidavit alleging that J.P. sustained major organ failure due to an immunologic condition (HLH) caused-in-fact by the vaccines at issue. Pet. Ex. 3 at ¶ 3. Petitioner further stated that, in accordance with the Program requirements, J.P. "suffered residual effects or complications [as a result of his condition] for more than [six] months after the administration of the vaccine, . . . and [that] J.P. died as a result of the administration of the vaccines. Id. at ¶ 4.

An initial status conference was held before the undersigned on May 21, 2015. During the status conference, respondent requested that petitioners file additional relevant medical records, including proof of vaccination and genetic testing results performed on J.P.'s sibling. Petitioners were ordered to file the requested medical records and a Statement of Completion indicating that all medical records necessary to substantiate the petition have been filed. See Scheduling Order, filed May 22, 2014. Respondent was ordered to file a Rule 4(c) Report. Id.

On June 2, 2014, respondent filed a Rule 4(c) Report in which she argued that this case is not appropriate for compensation under the terms of the Vaccine Act, as petitioners had not proven a Table injury or shown by preponderant evidence that J.P.'s condition and death was actually caused by the vaccinations. Resp. Rep. at 1, 10. Pursuant to Vaccine Rule 5, a telephonic status conference was held on July 1, 2014, during which the undersigned provided his preliminary views on the strengths and weaknesses of each party's position. Petitioners had yet to file the requested medical records, so they were ordered to file the outstanding medical records, a Statement of Completion, and an expert report addressing the *Althen*[2] criteria. See Scheduling Order, filed July 2, 2014.

On August 14, 2014, petitioners filed the genetic testing results and vaccination records as exhibits four and five, respectively. On September 25, 2014, petitioners filed a Statement of Completion, indicating that all relevant medical records in this matter had been filed. Petitioners were then ordered to file an expert report by November 24, 2014. On that day, petitioners filed a motion for a decision on the record. Respondent was given until December 11, 2014 to file a response. She did not do so. This case is now ripe for a decision.

[2] *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

II. Factual History

J.P. was a healthy twelve-year-old boy with an unremarkable medical history at the time of his vaccinations. See Pet. Ex. 2 at 21. On October 4, 2012, he visited Partners HealthCare System where he received the hepatitis A ("Hep A"), tdap, meningococcal, and influenza ("flu") vaccines in anticipation of a trip to Chalatenango, El Salvador. Pet. Ex. 2 at 479; Pet. Ex. 5 at 1. Between October 5, 2012 and October 12, 2012, J.P. and his family visited El Salvador. See Pet. Ex. 2 at 21. While there, J.P. drank only bottled water, although he brushed his teeth with tap water, and ate fresh fruits and vegetables. Id. at 438. He had contact with cows, chickens, and dogs. Id. He denied eating exotic food, swimming, or having contact with pigs or exotic animals. Id. He received multiple mosquito bites while abroad. Id.

On November 26, 2012, while in school, J.P.'s teacher noticed he was jaundiced. Id. He was taken to Chelsea Urgent Care for yellow sclera, vomiting, abdominal pain, and fever, reportedly since the day prior. Id. at 476. Lab tests showed markedly elevated liver function. Id. at 21. The urgent care center referred J.P. to Massachusetts General Hospital emergency department. Id. at 21, 476.

At the hospital, J.P.'s parents reported that he had some epigastric and right-upper-abdominal discomfort, nausea, and two episodes of non-bloody, non-bilious vomit since November 23, 2012. Pet. Ex. 2 at 21, 466. They also reported that he had developed dark urine around the same time, and had a few days of wet cough three weeks prior. Id. at 21.

J.P.'s liver function tests were abnormal, revealing markedly elevated bilirubin, direct bilirubin, aspartate aminotransferase, and alanine aminotransferase. Id. at 22. An ultrasound at that time showed a normal liver with thickening of the gallbladder wall, but no dilation of the ducts and no gallstones. Id. at 23. J.P. was transferred to the pediatric intensive care unit ("ICU") because he showed signs of liver damage.

J.P. was awake, alert and following commands upon admission to the ICU. Pet. Ex. 2 at 399. Studies for respiratory syncytial virus, parainfluenza, influenza, and adenovirus yielded negative results. Id. at 179-81. J.P.'s urine culture, blood culture, and plasmodium were normal. Id. His viral serology for causes of hepatitis was negative, as were tests for dengue fever, mycoplasma IgM, cytomegalovirus IgM, antinuclear antibodies, herpes type 1 and type 2 IgM, and human herpes virus 7. Id. at 128, 131, 134-35, 392. J.P's treating doctors were concerned that his liver failure might be secondary to the development of HLH,[3] based on lab tests showing a markedly elevated ferritin and elevated triglyceride level. Id. at 424. On November 29, 2012, a bone marrow biopsy revealed "evidence of hemophagocytosis consistent with HLH." Id. at 201, 425, 547. On November 30, 2012, Dr. David Ebb assessed J.P. as meeting the diagnostic criteria for HLH and recommended expeditious treatment for the disease. Id. at 425.

[3] Hemophagocytic Lymphohistiocytosis ("HLH") is a life-threatening immunological disease characterized by the ingestion and destruction of blood cells by the immune system. This disorder is "usually seen in children secondary to infection and [is] often fatal; [it] can also be secondary to rheumatologic or other conditions, or can be familial." Dorland's Illustrated Medical Dictionary 841, 1085 (32d ed. 2012).

On November 29, 2012, a liver biopsy showed "panlobular acute hepatitis. There [was] no morphological evidence of [HLH] in this biopsy." Id. at 545. J.P.'s pathologist concluded that "the differential diagnosis included infectious/viral hepatitis, toxic/drug injury and less likely autoimmune hepatitis." Id. The pathologist also concluded that the overall changes did not support a diagnosis of Wilson disease. Id. An MRI taken the same day showed heterogeneous enhancement of the liver consistent with acute hepatitis and enlargement of the spleen. Id. at 442.

Also on November 29, 2012, J.P. underwent an infectious disease consultation with Dr. Emily Lynch and Dr. Warren Shaw. Their impression was J.P. was suffering fulminant hepatic failure. Pet. Ex. at 443. "Overall he clinically appear[ed] well, but his labs [were] suggestive of disseminated intravascular coagulation or a bacterial infection . . . ." Id. The doctors opined that "[g]iven his recent travel[,] infectious etiology is likely." Id. The doctors considered a Hepatitis A infection—noting: "[h]epatitis A would fit the clinical picture and time course, however this would be extremely unlikely with negative Hep A IgM." Id. Other diseases in J.P.'s differential diagnosis included dengue and yellow fever, leptospirosis, salmonella typhi, or a parasitic etiology. Id.

On November 30, 2012, J.P. experienced a "rapid decline in mental status." Pet. Ex. 2 at 399. He had some initial improvement, but "quickly relapsed with grade II-III encephalopathy."[4] Id. at 23. A consulting neurologist noted that J.P. had "severe hepatic and likely uremic encephalopathy." Id. at 198. It was also noted that both liver failure and HLH could lead to an altered mental status. Id. at 401.

On December 1, 2012, J.P. underwent a neurology consult due to his change in mental status. Id. at 399. He was noted to be more somnolent in the morning of November 30, and by evening, was having hallucinations and aggressive behavior. Id. He was intubated out of concern for his ability to protect his airway and worsening mental status. Id. He was also placed on Versed and Fentanyl for sedation. Id. J.P's treating physician noted a "brief tonic arm extension in the setting of hyperextension," with no other change in vitals. Id. A head CT found no abnormalities. Id.

J.P. experienced numerous complications over course of his hospitalization. He suffered hospital-acquired RSV infection, aspiration pneumonia, acute renal failure, worsening encephalopathy, and progressive hypotension. Pet. Ex. 2 at 21, 23, 196, 202, 527, 539, 553, 576, 580. His treatments included continuous hemofiltration, significant pharmacological blood pressure support, and endotracheal intubation/mechanical ventilation. Id. On December 22, 2012, his condition significantly worsened with hypotension followed by a pulmonary hemorrhage. Id. at 196. After multiple discussions with his treating physician, Dr. Phoebe Yager, J.P.'s family agreed to withdraw medications supporting his blood pressure and to withdraw ventilator support. Id.

On December 22, 2012, J.P. died. Pet. Ex. 2 at 23-24. His parents declined an autopsy. Id.

[4] Hepatic encephalopathy is graded in four stages based on the level of impairment of autonomy, changes in consciousness, intellectual function, behavior, and the dependence on therapy. Grade II–III encephalopathy is characterized by lethargy, inappropriate behavior, somnolence, unresponsiveness to verbal stimuli, confusion, and gross disorientation. See Nelson Textbook of Pediatrics 1413-14 (19th ed. 2011).

A final hospitalization summary indicated that J.P.'s principal diagnosis was HLH. Id. at 21. His death certificate stated that his cause of death was pulmonary hemorrhage of one day's duration, resulting from acute renal failure and HLH of approximately four weeks duration. Pet. Ex. 1 at 1.

III. Summary of the Parties' Arguments

Petitioners have submitted this case for a decision on the medical records alone, without offering an expert report to set forth a reliable medical theory of causation or to explain a logical sequence of cause and effect showing that the vaccines in question were the cause of the alleged injuries and death. See *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Neither have petitioners submitted evidence addressing a medically appropriate timeframe, as is also required under *Althen*. Id. Petitioners aver that "[a]fter further analysis of the medical records, science and expert consultation, [they] will not be filing a medical expert opinion" and would like a decision to be made on the record as it stands. Motion at ¶ 8.

Respondent contends that petitioners have failed to meet their burden of proof, as they have not provided sufficient evidence to establish a more likely than not causal connection between J.P's death and the tdap, hepatitis A, meningococcal, and flu vaccines he received on October 4, 2012. Resp. Rep. at 6. Specifically, respondent acknowledges[5] that J.P. "ultimately suffered an encephalopathy, which is a 'Table'[6] injury" for a tdap vaccine. Resp. Rep. at 6. However, according to respondent, J.P. did not suffer this injury within the requisite time frame of three days, as noted in the Table. Id.

Respondent further contends that (1) petitioners have not provided a reputable and reliable medical or scientific explanation in support of a theory of causation, (2) petitioners have not established a "logical" sequence of cause and effect implicating a vaccine, and that (3) petitioners have failed to establish an appropriate temporal association between vaccination and J.P.'s condition and death. Id. at 6-9.

IV. Analysis

a. Applicable Legal Standard for a Table Claim

In order to prevail under the Program, petitioners must prove either a Table injury or that

[5] In her Rule 4(c) Report, respondent argues against compensation for a Table encephalopathy claim because J.P. did not meet the "five to fifteen day" requirement corresponding with receipt of a "tdap" vaccine. See Resp. Rep. at 6. The undersigned notes that a Table encephalopathy is listed for "vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s)," and that a Table encephalopathy claim associated with the tdap vaccine must manifest within three days and not five to fifteen days. The respondent makes no argument as to whether the Table encephalopathy would apply to the tdap vaccine, which J.P. was given. Accordingly, that issue will not be addressed and is not necessary to the decision.

[6] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

a vaccine listed in the Vaccine Table was the cause-in-fact of an injury. Petitioners' vaccine claim is deemed a Table claim, and a presumption of vaccine causation attaches, when they allege that an injury listed in the Vaccine Injury Table occurs within the time frame set forth in the Table. See § 300aa-14; see also 42 C.F.R. § 100.3. If, however, petitioners allege an injury that is not listed in the Table, the vaccine claim is deemed a non-Table case, and there is no presumption of causation. Rather, petitioners must satisfy their burden of proof under *Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). See also, § 300aa-13(a)(1)(A).

b. Analysis of Petitioners' Table Encephalopathy Claim

Based on the record as a whole, the undersigned finds that petitioners have not established that J.P. suffered a Table encephalopathy, as the medical records indicate that J.P. did not suffer an encephalopathy within the relevant time frame for a tdap vaccine.

In a Table encephalopathy claim, petitioners must first demonstrate that the minor received a covered vaccine. Next, petitioners must demonstrate that the minor suffered an injury corresponding to the covered vaccine within the specified time period. Here, the Table lists an encephalopathy as an injury arising from a tdap vaccine if the injury occurs within three days of the vaccination. See 42 C.F.R. § 100.3(a). The definition of encephalopathy under the Vaccine Table is a more narrow interpretation than what is commonly accepted in the medical community. Under the Qualifications and Aids to Interpretation ("QAI") of the Vaccine Table, a Table encephalopathy occurs where the petitioner suffers an acute encephalopathy, followed by a chronic encephalopathy for more than six months, or death. 42 C.F.R. § 100.3(a)-(b)(2).

Under the Table, "[a]n acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). It must persist for at least twenty-four hours and must meet at least two of the following criteria: (1) a significant change in mental status, specifically a state of confusion, delirium, or psychosis, that is not medication related; (2) a significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and (3) a seizure associated with loss of consciousness. 42 C.F.R. § 100.3(b)(2)(i)(B).

J.P. received a tdap vaccination on October 4, 2012. On November 30, 2012, he experienced a "rapid decline in mental status" diagnosed as an encephalopathy on November 30, 2012. Pet. Ex. 2 at 399. The medical records note that his encephalopathy worsened in the days leading up to his untimely death on December 22, 2012. Pet. Ex. 23-24.

As respondent acknowledges, the encephalopathy J.P. suffered would meet the Table requirements, in that he was noted to have had a severe change in mental status characterized by hallucinations and aggressive behavior, and experienced a decreased level of consciousness due to his worsening mental status and increased somnolence, requiring intubation and sedation on December 1, 2012. See Pet. Ex. 2 at 399. It was also noted that J.P. suffered "brief tonic arm extensions in the setting of hyperextension," indicating possible seizure activity. Id.

Nevertheless and most importantly, J.P.'s encephalopathy did not occur until fifty-seven days after his vaccinations on October 4, 2012 and it appears that his encephalopathy was

secondary to a severe liver disease, HLH, which is not a Table injury. J.P.'s encephalopathy began in the morning of November 30, 2012 and continued into the following day, when he was then intubated and sedated. Id. To meet the requirements of the Table, the encephalopathy must have occurred within three days of a tdap vaccination. Accordingly, the petitioners cannot establish a Table encephalopathy based on the date of occurrence of the encephalopathic stages of his illness.

Not having the benefit of presumed vaccine causation, petitioners must therefore prove that the vaccines at issue caused-in-fact the alleged injuries and death.

c. Applicable Legal Standard for an off-Table Claim

When a petitioner alleges an "off-Table" injury, eligibility for compensation is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) a vaccine set forth on the Vaccine Injury Table was received; (2) the vaccine was received in the United States; (3) the person in question sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months or resulted in death. *See* § 11(c).

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of petitioners alone, unsubstantiated by medical records or medical opinion. See § 13(a)(1). To satisfy their burden of proving causation-in-fact in this case, petitioners must "show by preponderant evidence that the vaccinations brought about [J.P.'s] injury by providing: (1) a medical theory causally connecting the vaccinations and the injury; (2) a logical sequence of cause and effect showing that the vaccinations was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccinations and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); see also *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). Petitioners' must show that the vaccination was the reason for the injury. "A reputable medical or scientific explanation must support [a] logical sequence of cause and effect." *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the *Althen* prongs. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). However, mere temporal association is not sufficient to prove causation in fact. See *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

Petitioners have established that J.P. did receive a covered vaccine under the Vaccine Injury Table and that it was received in the United States. See Pet. Ex. 5. However, petitioners have failed to establish that the J.P.'s HLH, and ultimately his death, was caused by the hepatitis A, tdap, meningococcal and/or influenza vaccines he received on October 4, 2012.

d. Analysis of off-Table claim

i. *Althen* Prong One

Under the first prong of *Althen*, petitioners are required to set forth a reliable medical theory that explains how a particular vaccine or vaccines can cause the injury in question. *Althen*, 418 F 3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (holding that the purpose of the Vaccine Act's preponderance of the evidence standard "is

to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body"). However, a causation theory or mechanism must be proposed and supported by a sound and reliable medical or scientific explanation. *Knudsen v. Sec'y, HHS*, 35 F.3d 543, 548 (Fed Cir. 1994).

In this case, petitioners have not offered expert testimony of a theory explaining how the hepatitis A, tdap, meningococcal, and/or flu vaccines can cause any or all of J.P's conditions and his death. Without a medical theory to elucidate the circumstances by which a vaccine can cause a particular injury, there is hardly a basis to form a decision on causation; especially when, as in the case here, the decedent's medical records raise questions bearing on causation. For example, his treating doctors suggested the possibility that the cause of J.P.'s illness may have arisen from an infection acquired during his travel to El Salvador on October 5 through October 12, 2012. Considering that the petitioners have not provided a theory to explain how the vaccines or any one of them could cause the primary condition, HLH, they are unable to preponderate the evidence in their favor. *Althen* prong one fails.

ii. *Althen* Prong Two

The second *Althen* prong requires petitioners to establish that the vaccine was the reason for the injury—not only a but-for cause of the injury but also a substantial factor in bringing about the injury. See *Shyface v. Sec'y of HHS*, 164 F.3d 1344, 1352 (Fed. Cir. 1999). Impressions from treating physicians can be probative when evaluating the second *Althen* factor, as "treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

In this case, J.P.'s treating physicians—resident Dr. Emily Lynch and attending Dr. Warren Shaw—noted several possible causes of J.P.'s condition. Specifically, on November 29, 2012, the doctors documented:

> His clinical picture is not completely clear at this time. Given his recent travel infectious etiology is likely. Hep A would fit the clinical picture and time course, however this would be extremely unlikely with negative Hep A IgM. It is interesting that [J.P] has not mounted a measurable immunologic response to his Heb B series or his single Hep A vaccine. Because of this and clinical picture consistent with Hep A, we would recommend Hep A PCR and repeat serologies. Other infectious processes that would be possible are dengue and yellow fever however these are much less likely given the time course as they typically have a short incubation period. Although not necessarily associated with travel, Leptospirosis is another infectious cause of hepatic failure and should be considered. Salmonella typhi does not normally cause such a marked rise in LFT's however given the hepatosplenomegaly and his travel we would recommend further evaluation with stool cultures. His current antibiotics of cefotaxime and vancomycin

> should be sufficient at this time. It is also unlikely but possible that this could be parasitic so we would recommend stool O&P.

Pet. Ex. 2 at 443. The doctors stated that a hepatitis A infection would fit J.P.'s clinical picture, however, they expressly noted that it would be "extremely unlikely with negative Hep A IgM." Id. Additionally, the doctors noted that J.P. did not mount a measureable immunologic response to hepatitis B or hepatitis A vaccinations. Id. Thus, the doctors turned to other likely causes of J.P.'s condition; including, dengue and yellow fever, leptospirosis, salmonella typhi, or a parasitic etiology. Id. Ultimately, no specific cause was identified for the fatal illness.

To prove causation under this prong, there must be more than a mere possibility of a connection. Here, the only vaccine discussed by J.P's treating physicians, relevant to this claim, is the hepatitis A vaccine. First, the doctors expressly determined a possible hepatitis A infection was unlikely, based on blood testing for the antibody, and that J.P. likely acquired an infectious disease from his travel to El Salvador. Second, the record also notes that J.P. mounted a poor immunological response to his hepatitis A vaccination. Elsewhere in the record, this poor response is attributed to unfavorable timing between vaccine administration and a possible wild hepatitis A infection. Id. at 459. Thus, at least two of J.P.'s treating physicians believed his vaccination had no effect in providing immunity against acquiring a wild Hepatitis A infection—leading to the logical conclusion that the vaccine could not have caused J.P.'s condition. More significantly, the records reveal that J.P.'s treating physicians' primary hypothesis on the cause of his condition focused on his travel to El Salvador and not his vaccinations.

It is also clear from the record that J.P.'s encephalopathy was secondary to his HLH, which also caused severe liver damage. Petitioners have not provided an expert report explaining how the vaccine can cause HLH and a subsequent encephalopathy. Accordingly, based on the entire record, the undersigned finds that there is insufficient evidence to enable a conclusion of vaccine causation.

iii. *Althen* Prong Three

The third *Althen* prong requires the petitioners to demonstrate that the injury "occurred within a medically acceptable time frame." *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1358 (Fed. Cir. 2006). Petitioners must establish a proximate temporal relationship, which "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The appropriateness of timing of the onset of symptoms is fairly specific to the diagnosis and the alleged vaccine.

An appropriate time frame in a causation-in-fact claim differs from that of a Table claim because an appropriate time frame in the former is based largely on a proposed medical and scientific theory of causation. Petitioners here have offered no evidence of a medically appropriate time frame to infer vaccine causation. The medical records show that J.P. began to experience symptoms related to his illness around November 20, 2012, forty-seven days after his vaccinations on October 4, 2012. Without an expert opinion explaining how this is medically appropriate, based on a medical theory specific to his diagnosis of HLH leading to liver damage, encephalopathy and

death, there is no basis to conclude that the petitioners have satisfied *Althen* prong three.

V. Conclusion

The facts of this case are truly unfortunate and sad. Still, the legal burden, as established by the Table and case law, remains. The medical records do not provide adequate support for finding petitioners have established a Table encephalopathy claim, as the apparent onset is outside the specified time frame for the tdap vaccine. Further, the minor's encephalopathy appears to have been secondary to HLH, a very severe and debilitating illness for which no expert opinion has been provided to support causation. Accordingly, petitioners do not benefit from a presumption of vaccine causation. Concerning the evidence to establish an off-Table claim, petitioners have not provided a medical expert opinion to satisfy their burden under *Althen*, and the medical records alone do not preponderate the evidence in petitioners' favor. Therefore this case must be **DISMISSED**.

The Clerk shall enter judgment accordingly.[7]

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master

[7] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.